

REMARKS

The remainder of this reply is set forth under appropriate subheadings for the convenience of the Examiner.

Claim Amendments

Claim 1 has been amended to include limitations from dependent claim 12 of inserting a distraction instrument into the intervertebral space of a human body using a midline marker as a guide, selecting an artificial disc for implantation, and inserting the artificial disc in the intervertebral space using the midline marker as a guide. Support for this amendment to independent claim 1 can be found in, in addition to claim 12, the specification at page 16, lines 1-17, and page 14, line 4 through page 15, line 26.

Claim 5 has been cancelled. Claims 6, 7, and 9 have been amended to depend from independent claim 1, rather than from claim 5. Claim 11 has been cancelled and dependent claim 12 has been amended to be consistent with amended independent claim 1 and to depend directly from independent claim 1.

Claim 8 has been amended to delete the term “pin” and to substitute therefor “midline marker” to more particularly point out and distinctly claim the invention. Support for this amendment can be found in the specification at page 13, lines 12 through 21.

No new matter has been added.

Election/Restrictions

Applicants acknowledge withdrawal of claims 14-53, and reserve the right to file divisional applications directed to the withdrawn subject matter.

Rejection of Claim 8 under 35 U.S.C. § 112, Second Paragraph

Claim 8 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards to the invention. Specifically, the Examiner stated that claim 8 recites the limitation “pin insertion instrument” without antecedent basis.

Claim 8 has been amended to substitute the term “pin” with the term “midline marker.” Further, claim 8, as amended, now states that the trial spacer insertion instrument is contacted with “a midline marker insertion instrument” rather than “the pin insertion instrument.” As amended, dependent claim 8 provides proper antecedent basis. Support for this amendment of dependent claim 8 can be found in the specification at page 13, lines 12-21. No new matter has been added. As amended, dependent claim 8 obviates the basis for rejection of this claim under 35 U.S.C. § 112, second paragraph.

#### Incorporation of Subject Matter by Reference

The Examiner stated that Applicants’ attempt to incorporate subject matter into this application by reference is ineffective because the referenced materials also incorporate by reference, and that it is inappropriate practice to incorporate by reference any reference which itself incorporates by reference. For support, the Examiner referenced 37 C.F.R. § 1.57(c) directed to “essential material.” None of the material incorporated by reference by Applicants in the specification is “essential material.” As described in the Manual of Patent Examining Procedure (MPEP) at Section 608.01(p), “essential material” is defined as follows:

“Essential material” is defined as that which is necessary to 1) describe the claimed invention 2) provide an enabling disclosure of the claimed invention, or 3) describe the best mode (35 U.S.C. 112).”

Applicants do not consider any of the material incorporated by reference to be “essential material” as that term is defined by the MPEP. Therefore, Applicants do not view amendment of the specification as being necessary.

#### Claim Objections

The Examiner objected to claims 12 and 13 as being dependent upon a rejected base claim, but allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

Applicants acknowledge the Examiner's statement with respect to claims 12 and 13. As described below, independent claim 1 has been amended to include the pertinent limitations of dependent claim 12. As amended, it is believed that independent claim 1 meets the requirements of 35 U.S.C. § 102 and 103 in view of the references cited by the Examiner, taken either separately or in combination. The remaining pending claims under consideration are dependent, directly or indirectly, from independent claim 1 and are believed to be, along with claim 1, in condition for allowance.

Rejection of Claims under 35 U.S.C. § 102(b) and 102(e)

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,224,599, issued to Baynham, *et al.*. In particular, the Examiner stated that Baynham, *et al.* discloses a method of fixing a midline marker (104) to a face of an intervertebral body, as shown in Fig. 5 of Baynham, *et al.*. Applicants' Claims 1, 2, and 5-11 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2002/0161366 (by Robie). In particular, the Examiner stated that Robie discloses attaching a template (50) to a vertebral body as a midline marker, where the midline marker is inserted in the guide of Fig. 4A and impacted until embedded in a vertebral body.

Baynham, *et al.* teach a device and method for forming an axis port between vertebrae wherein a wedge 102 is adapted for insertion within channel-defining means 104. An impactor handle 106 is employed to direct the wedge 102 and channel-defining means 104 between vertebrae. Thereafter, wedge 102 is withdrawn from channel-defining means 104, thereby leaving an axis port defined and supported by channel-defining means 104. Specifically, as stated at column 3, lines 41-48:

The channel defining means distal end 118 includes wedge-shaped wall members 126, 126' extending from said proximal end and further includes pairs of coplanar edges in converging relationship 128, 130, and 128', 130' defining one or more angles of convergence. The edges are effective to maintain a particular vertebral space after slidable disengagement of wedge 102, thereby defining a convenient axis port with an intervertebral space.

Applicants' independent claim 1 has been amended to include the step of inserting a distraction instrument into an intervertebral space using a midline marker as a guide. An artificial disc is selected for implantation and then inserted in the intervertebral space using the midline marker as a guide.

There is no disclosure or suggestion in Baynham, *et al.* of fixing a position of a midline marker relative to a face of a vertebral body for instrument alignment and artificial disc placement, and inserting a distraction instrument into an intervertebral space using the midline marker as a guide, as claimed by Applicants. Rather, Baynham, *et al.* teach only collective introduction of an assembled wedge and channel-defining means, followed by disengagement of the wedge from the channel defining means to thereby form an axis port, as stated Col. 3, line 66 through Col. 4, line 5 and with reference to Fig. 5, which was referenced by the Examiner:

Fig. 5 shows a post insertion view of adjacent vertebrae 502 and 503, wherein subsequent to insertion of the assembled wedge-distracter channel device 100 (as depicted in Fig. 4) the wedge 102 is slidably disengaged from the channel defining means 104, resulting in the creation of an axis port 500. Various surgical procedures are facilitated by formation of this means of easy ingress and egress.

There is no disclosure or suggestion of use of channel defining means 104 as a guide before insertion of a distraction instrument, such as wedge 102. Therefore, Baynham, *et al.* do not teach Applicants' invention as claimed in amended independent claim 1.

Robie, *et al.* teach insertion of a distracter into an intervertebral space, followed by placement of template 50, which the Examiner refers to as a "midline marker" over distracter 10. Template 50 is then engaged which adjacent vertebral bodies are being distracted, and once template 50 is in place, distracter 10 is withdrawn, leaving template 50. Specifically, as stated at paragraph 58:

After the appropriate distracter 10 has been placed into the interdiscal space, the handle 70 is assembled to the appropriately sized template 50.

ball detents 58 of the template 50 indicate the appropriate orientation of the handle 70 with respect to the template 50. This assembly is then placed over the distracter 10 and slid into place. As shown in Fig. 7, a mallet is used with the handle 70 to impact the template 50 into the intervertebral body. The prongs 56 on the template 50 engage the adjacent vertebral bodies and hold the template 50 in place. Impaction continues until the template 50 bottoms out on the distracter 10. This fixes the position of the template 50 relative to the posterior edge of the distracter 10. The handle 70 is then rotated 90 degrees. The ball detents 40 from the distracter 10 engage the handle 70, indicating the appropriate position. The distracter 10 is then withdrawn, leaving the template 50.

As stated at paragraph 61, implant 20 is passed through template 50 to thereby place implant 20 between the distracted vertebrae:

The following steps describe insertion of a single implant 110. Placement of the implant 120 is typically along the midline, on a sterile table, the hole(s) of the appropriately sized implant 120 is stuffed with the already harvested autologous bone. The implant 120 is then placed on an inserter 121. As shown in Fig. 10, the implant 120 is passed through the template 50, into the space and the inserter 121 removed. The implant 120 is fully seated using a tamp 122 as shown in Fig. 11.

As with Baynham, *et al.* there is no disclosure or suggestion in Robie, *et al.* of fixing a position of a midline marker relative to a face of a vertebral body for instrument alignment and artificial disc placement, and inserting a distraction instrument into a vertebral space using a midline marker as a guide. Therefore, as with Baynham, *et al.*, Robie, *et al.* do not anticipate Applicants' invention as set forth in amended independent claim 1. Remaining rejected pending claims 2 and 6-10 depend directly or indirectly from independent claim 1 and, accordingly, also are not anticipated by the teachings of Robie, *et al.* in view of independent claim 1 as amended.

#### Rejection of Claims Under 35 U.S.C. § 103(a)

Claims 3 and 4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Robie, *et al.* in view of U.S. Publication 2002/0058944 (Michelson). Specifically, the Examiner stated that Michelson teaches use of radiography in the field of endeavor or analogous art of surgery to that of Applicants' claimed method, and that it would have

been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of radiographical markers, as taught by Michelson to aid in radiographical visualization as per Robie, *et al.* in order to ensure the implant is aligned properly and to verify the implant.

Claims 3 and 4 depend from amended independent claim 1. Michelson does not remedy the deficiencies of Robie, *et al.* as applied to Applicants amended independent claim 1. Therefore, the subject matter of claims 3 and 4, which depend from Applicants' amended independent claim 1 is not obvious in view of Robie, *et al.* or Michelson, taken either separately or in combination. Dependent claims 3 and 4 meet the requirements of 35 U.S.C. § 103(a) in view of Robie, *et al.* and Michelson, taken either separately or in combination.

#### SUMMARY AND CONCLUSIONS

Applicants have amended the specification to correct minor informalities. Further, independent claim 1 has been amended to include limitations from dependent claim 12 and its intervening claims. Other pending claims have been cancelled or amended, as appropriate, in view of the amendments to independent claim 1. Dependent claim 8 has been amended to correct an error in antecedent basis. Amendment of the specification and the claims has included no new matter.

As amended, independent claim 1 and remaining pending claims dependent therefrom are novel and nonobvious in view of the prior art of record, including the references cited by the Examiner. Therefore, the remaining pending claims meet the requirements of 35 U.S.C. § 102(b), 102(e), and 103(a). Further, as amended, dependent claim 8 particularly points out and distinctly claims what the inventor considers to be his invention and therefore meets the requirements of 35 U.S.C. § 112, second paragraph.

It is believed that the application is now in condition for allowance and reconsideration and withdrawal of the outstanding rejections respectfully is requested. If the Examiner believes that a telephone conference would expedite prosecution, he is invited to call Applicants' undersigned attorney.

Respectfully submitted,

HAMILTON, BROOK, SMITH &  
REYNOLDS, P.C.

By 

N. Scott Pierce  
Registration No. 34,900  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: 6/27/06